

REMARKS

In view of the foregoing amendments and the following representations, reconsideration and allowance of the above-identified application is respectfully requested.

Claims 1, 4-12, 15-33 are in the present action. In the present response, Applicants have amended the claims to clearly indicate that the claimed active pellet employs an inert starting seed with a mesh size between 18-20 and that the antifungal agent is itraconazole or saperconazole.

On page 2 of the Office Action the Examiner rejected claims 1-33 under 35 U.S.C. § 103(a) as being unpatentable over the teachings of Namburi et al., United States Published Patent Application No. 2002/0150620 ("Namburi").

In response to this rejection Applicants have amended the claims to specifically indicate that the recited inert starting seed is an 18-20 mesh size and that the antifungal agent is itraconazole or saperconazole. No new matter is added by this amendment. Support can be found in claims 3 and 14 as originally filed and on page 3, lines 23-25 of the specification. Because this size limitation appeared in claims 3 and 14 these claims have been canceled without prejudice. In addition, the claims that depended upon canceled claims 2, 3, 13 and 14 have been amended to depend from the amended independent claims. Claims 8, 19 and 32 have also been amended to correct obvious typographical errors

Applicants respectfully submit that the pending claims are patentable over the Namburi reference because the Namburi reference does not disclose or suggest an

itraconazole or saperconazole active pellet that employs an 18-20 mesh inert starting seed as recited in the pending claims.

The Namburi references discloses a process for making itraconazole formulations that employ an alcohol and strong acid solution. Namburi, ¶ 10. The Examiner correctly indicates that the Namburi references discloses the use of an inert starting seed in the wide range of 100 to 1000 micrometers in diameter. Namburi, ¶ 19. However, paragraph 19 of the Namburi reference further states that the preferred diameter of the starting seed is 600 to 250 micrometers (30-60 mesh) or 700 to 600 micrometers (25-30 mesh). In addition the actually working example employs Celpheres CP 507 (¶ 33) which is a microcrystalline cellulose sphere with an average diameter of 500 to 710 micrometers. See Exhibit A which is a compilation of information obtained form the internet regarding Celphere CP 507.

This small starting seed diameter described and embodied in the Namburi reference is consistent with the conventional teachings for itraconazole pellets. For example, United States Patent No. 5,633,015, which is discussed on page 1 of the subject application, teaches that a small diameter starting seed, i.e 25-30 mesh, is critical for preparing an itraconazole pellet. United States Patent No. 5,633,015 states:

The particular size of the cores is of considerable importance. On the one hand, if the cogs are too large, there is less surface area available for applying the drug coating layer, which results in thicker coating layers. This raises problems in the manufacturing process as an intensive drying step is needed to reduce residual solvent levels in the coating layer. The intense drying conditions may adversely effect drug dissolution from the beads and should therefore be controlled extremely well during the manufacturing process. On the other hand, small cores have a larger total surface available for coating resulting in thinner coating layers. Consequently a far less intensive drying step can be used to decrease residual solvents levels. Cogs which are too small, e.g. 30-35 mesh cores, however, have the disadvantage of showing considerable tendency to

agglomerate during the coating process. Therefore, 25-30 mesh cons represent the optimum size where neither agglomeration nor an intensive drying step unduly constraint the manufacturing process.

United States Patent No. 5,633,015, Col. 1, line 58 to Col. 2 line 8 (emphasis added).

The pending claims require the use of an inert starting seed that is larger than the preferred ranges taught by the Namburi reference and United States Patent No. 5,633,015.

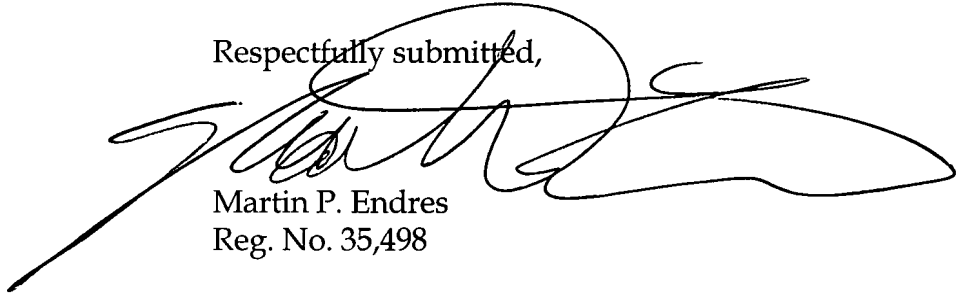
The size of the starting seed recited in the pending claims is 18-20 mesh or 850 to 1000 micrometers. See Exhibit B for the mesh micrometer conversion chart.

Contrary to the teachings of the prior art, Applicants have surprisingly discovered that itraconazole pellets can be made with a large starting seed. The use of the larger starting seed as recited in the pending claims is not specifically disclosed or suggested by the prior art. Therefore, it is respectfully submitted that the amended claims are patentable over the Namburi reference.

Based upon the foregoing amendments and representations, Applicants respectfully submit that the rejection of the claims in the above-identified application have been overcome and should be withdrawn. Early and favorable action is earnestly solicited.

It is believed that no fee is required for submission of this response because it is being mailed before the three month deadline, April 12, 2007. If a fee is due, the Commissioner is authorized to charge our deposit account, Account No. 08-1540.

Respectfully submitted,

A large, stylized handwritten signature in black ink, appearing to read 'Martin P. Endres', is written over the text 'Respectfully submitted,'.

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